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April 1, 2000

Food and Drug Administration
Dockets Management Branch (HFA-305)
5630 Fishers Lane
Room 1061
Rockville, Maryland 20857

RE: Docket No. 00D-0053

Dear Sir or Madam:

Alliance Medical Corporation respectfully submits the following comments in response to the Food and Drug Administration's (FDA) draft guidance documents entitled "reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme;" and "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals" – [65 Fed Reg. 7,027 (Feb 11, 2000); hereafter, "draft guidance documents"]. Alliance Medical Corporation is a Phoenix, Arizona-based Third Party Reprocessor of medical devices labeled for single use, who is registered with the FDA. In addition, Alliance is a founding member of the Association of Medical Device Reprocessors (AMDR). Alliance believes that it is the second largest company doing reprocessing in the United States.

Alliance is pleased to have the opportunity to provide comments on FDA's draft guidance documents. Alliance supports totally the comments of AMDR, and the Agency should consider the following remarks as additional information and/or further clarification of various issues.

Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme

Page 2

In paragraph 2, FDA says, *"FDA **anticipates** using the RPS in the future in response to requests from the **public** on the category of a reprocessed SUD not listed on Appendix 2. Such requests should be directed, in writing, to the contact noted in the Preface. FDA will **periodically publish a revised list** of categorized devices based upon these requests."*

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Comments:

First, Alliance is confused as to why FDA would consider future revisions to the RPS. The current draft document is intended to be a means of determining when FDA will begin enforcement of the requirement for premarket notification, following implementation of the Final Guidance Document. Once the Guidance Document has been implemented (i.e. published in the Federal Register), Alliance is not sure what value there is in revisiting the implementation schedule. Is it the Agency's intention to continue with selective enforcement into the future?

If the agency does decide to retain this concept of reviewing and revisiting the RPS, Alliance requests that FDA look at the following questions surrounding the above mentioned statement, and provide a clearer picture of the statement's wording.

- What does "anticipates" mean?
- "requests from the **public"** – Why the public? What protection does the third-party reprocessor have from the OEM? What about requests from the third-party and the hospitals?
- "periodically publish a revised list" – How often is "periodically"? What if a reprocessor or hospital is working on a submission of a device in the "moderate" category, and the "revised list" moves it to "high"?

Second, Appendix B (or 2) ["List of frequently reprocessed SUDs and their risk category according to the risk categorization scheme from the companion Risk Scheme guidance (attachment 2)"] shown in both documents has many inaccuracies. For example, a number of devices that are identified as High Risk should be regarded as Moderate or Low Risk, based on our efforts to use the algorithm to establish the risk level. Therefore, Alliance respectfully requests FDA to make public all worksheets used to establish device risk levels. Where we differ on the assessment, we would appreciate the opportunity to comment on those differences. Later in this document, Alliance will give specific illustrations of these problems and provide an alternative to creating the "Frequently Reprocessed SUDs" listing.

At the bottom of page 2: *"FDA will consider any SUD* ***not on the current list or subsequently revised lists to be one that POSES A HIGH RISK*** *if reprocessed."*

Comments:

As mentioned above, Alliance believes that a better source of information concerning products that are, or could be, reprocessed already exists. Specifically, the description of devices in Title 21, Part 800 of the Code of Federal Regulations, which includes the device classification, is available for download from CDRH. Therefore, Alliances respectfully requests FDA to amend the above-referenced statement to allow the device classification to stand. By doing so, FDA will be, in essence, calling for PMAs on Class III devices, and Premarket Notifications for Class II or Non-Exempt devices.

In Appendix B, which used both the Regulation Number and Product Code ("ProCode") information, there are numerous instances in which one or more errors exist, for example:

- The names of many of the devices in Appendix B do not match a device name in the CDRH data.

- Multiple device names having the same Regulation Number and same ProCode letters are use.

  Example: Under Cardiovascular, "needle" and "trocar" (two separate entries) both have the same Regulation Number (870.1390) and the same ProCode (DRC). Both items are correctly shown as Class II and requiring 510(k). Yet a needle was given a risk category "High" and the trocar "Moderate".

  From Alliance's positions in trying to comment, we can only tell the Agency that our company does not reprocess a used, ported trocar today because we do not currently know how to successfully clean it. In contrast, Alliance does reprocess a used "non-ported trocar". This is a device that looks like a big nail or spike; stainless, no ports, no hard to clean areas, etc. Alliance's risk assessment would be low risk.

  What is the Agency's definition of a "needle"?

  Example: Under Cardiovascular, "Electrophysiology recording catheter", the Regulation Number should be 870.1220, not "870.1120".

  Example: Under Gastroenterology/Urology, "non-electric biopsy forceps" (876.1075) is Exempt (Y), Class I, as opposed to "N" and "II".

  Example: Under OB-GYN, "laparoscopic dissectors", "laparoscopic graspers", "laparoscopic scissors", and **"trocar"** all have the same Regulation Number (884.1720) and the same ProCode (HET), yet the dissectors and trocar have a risk of "low," and the graspers and scissors have a risk of "high". The definition for Regulation Number 884.1720 is "Laparoscope, Gynecologic (and Accessories)".

  Example: Under Surgery, "biopsy forceps" are shown as having a Regulation Number of "876.1075", Exempt ("N"), Class "II". As previously pointed out above, 876.1075 is also called "non-electric biopsy forceps" with the same incorrect information.

  Example: Under Surgery, "endoscopes" (876.1500) has listed under ProCode "many". Alliance's search of the CDRH data indicates the following ProCodes:

  EXZ, FAJ, FAK, FAL, FAM, FAN, FBI, FBK, FBN, FBO, FBP, FCC, FCO, FCP, FCQ, FCR, FCW, FCX, FCY, FCZ, FDA, FDC, FDE, FDF, FDP, FDR, FDS, FDT, FDW, FDX, FDY, FDZ, FEA, FEB, FEC, FED, FEI, FEJ, FEM, FEQ, FER, FET, FFS, FFY, FFZ, FGA, FGB, FGC, FGS, FHO, FHP, FHX, FJL, FTI, FTJ, FTK, GCF, GCG, GCH, GHI, GCK, GCL, GCM, GCN, GCO, GCP, GCQ, GCR, GCS, GCT, GCW, GDB, KDM, KDO, KGD, KOG, MNK, MNL

Attached, as Exhibit "A" to this document is Alliance's listing of "Most Frequently Reprocessed Devices", using the total CDRH database. As is the case with endoscopes, only those ProCodes which Alliance *currently or may soon reprocess* have been included.

Important Point: Just as not all ProCodes will be items that can or should be reprocessed, neither will all ProCodes have the same risk assessment. And in fact, as pointed out in the AMDR Comments and in Alliance's first comment above, there appears to be a need for further discussion and interpretation of the questions used by the Agency in its initial attempt at setting risk.

Page 3 – Scope

At the bottom of the page, FDA says, *"In the **near future**, FDA **intends to examine** whether it should include other establishments that may reprocess SUDs."*

- What is "near future"? Alliance suggest that the Final Guidance Document include all parties that reprocess and if necessary, extend the deadlines for filing submissions by type of reprocessor. In this way, everyone will know on the front end what the "rules of the game" are at the beginning, and the Agency will ensure uniformity throughout the process.

- "intends to examine" – The issue should not be "who", but "if" one reprocess. To set the list of devices for hospitals and third-party reprocessors today, and then perhaps a separate set of requirements for surgery centers, rehabilitation hospitals, physician offices, public health departments, home health agencies, contract management companies of central sterile departments, etc. will only lead to loopholes that the Agency will continually be trying to close. Alliance recommends that the Final Guidance Document cover "all locations where reprocessing takes place". FDA may elect to phase in the enforcement of the Guidance, but the policy will be consistent.

Page 4 – General Approach

FDA says, *"It is important to note that many of the questions asked in the flowchart **may require subjective responses**. Despite the **possibility** of different interpretations, FDA has **tried** to make consistent categorizations across all SUD types."*

- "**may** require subject responses" – Did Appendix 2 include or not include "subject responses"? If so, who? What input did FDA get?

- "**possibility** of different interpretation, FDA has **tried** . . . " – Did the current risk assessment in Appendix 2 include "subjective responses"? Is there a "possibility" that some of FDA's current risk assessments are wrong because of "different interpretations"? If so, what is the appeal process?

Comments:

Alliance believes that all parties would be better served by dropping the "Risk Scheme". In its place, the utilization of the existing Class I, Class II, and Class III device classification with

appropriate timeframes assigned would be a clearer approach. A close review of the Appendix B (or 2) shows that very few items would move in timing if this approach were adopted. In addition, should the Agency have specific devices for which they have concerns that the submissions need to come in more quickly, CDRH could publish that listing, along with the answers to Worksheets 1, 2, & 3 that support the reasoning for acceleration of the submission. Once available for public comment, the Agency could see any areas where disagreement on the FDA-assigned risk level exists.

In the AMDR Comments, the Agency will see numerous examples differences of opinion as to the proper classification of all the devices currently listed as "High".

Finally, there will be numerous new devices added to the listing during this comment period, and by adopting the above recommendation (Class I, II, II vs current proposal), all newly identified items will have an assigned timeframe for submission of data.

Page 4 – Flowchart 1: Evaluating the Risk of Infection (Appendix 1)

FDA says, *"Flow chart 1 evaluates the risk of infection posed by reuse of a SUD following reprocessing."*

Comments:

This statement fails to ask the question, "What type of reprocessing, and by whom?" Certainly, the "risk of infection" is higher if the reprocessing is done in a physician's office as opposed to the hospital or the third-party reprocessor. GI Biopsy Forceps reprocessed by a freestanding GI Lab (outside the hospital) will be far more risky that if it is reprocessed by a third –party reprocessor such as Alliance. Yet, physician-owned outpatient surgery centers and practices would be exempt under the current draft document.

Page 6 – Question 3: Does the SUD include features that could impede thorough cleaning and adequate sterilization/disinfection?

Comments:

This question begs for further clarification.

- Cleaned by whom?
- What is "impede"? Perhaps a more appropriate word would be "prohibit" or "prevent".
- How "narrow" is narrow?
- What is "readily accessed"?
- What method of cleaning? Manual, mechanical, and custom-built fixtures must be added to the equation.

But perhaps a bigger question in the view of Alliance is the fact that should a device "include features that could impede thorough cleaning and adequate sterilization/disinfection", one

would only know this fact by the use of a validated cleaning procedure. Perhaps a better question is:

> *"Does or can a cleaning process be identified that is repeatable with predicable results that will result in a SUD that is clean and ready for sterilization/disinfection?"*

Page 6 – Question 4: Does a reusable device exist that has an equivalent design and the same intended use as the SUD?

Comments:

The term "same intended use" should be further defined. If CDRH were to ask the OEM, they would say NO to the question every time, because to them, the "intended use" of a SUD is for one use only. The intended use of a reusable is multiple uses. Alliance as always believed that the reprocessing of single-use medical devices makes the device functional for its intended clinical use for *one more single-use.*

Furthermore, FDA goes on to say, *"In some circumstances, there will be cleared, approved, or exempt reusable devices, (including designs with problematic construction or materials features) that are equivalent to a SUD with the same intended use. In this case, the risk is diminished because it is evident that cleaning and sterilization / disinfection can be accomplished with the reprocessed SUD by using techniques directed by labeling for the reusable device.* ***If the answer to question 4 is "Yes", then the risk of infection is low."***

But this logic does not hold true when one looks at Appendix 2. For example the "non-electric biopsy forceps" (page 28) says under Exempt – "NO", which has previously been pointed out as an error. Second, the Risk Category is "high", when it is known that there is a reusable counterpart. So why is it not "low" per the above question?

SUGGESTION: CDRH should hold a one or two day working session to **collectively** (OEMs, third-party reprocessors, hospitals and FDA) look at each device for which FDA finds troublesome from the standpoint of setting the timeframes for submission of 510(k)/PMA data. As previously mentioned, Alliance does not believe that every device requires this intense evaluation.

Page 7 – Flowchart 2: Risk of Inadequate Performance (Appendix 1)

FDA says, *"For a reusable device, the OEM validates that the device will perform without failure for the number of times it is labeled to be reused."*

Comments:

Alliance respectfully disagrees with the Agency on this position. It implies that all devices have a predetermined "number of uses". Such is not the case. Does the labeling for a reusable Biopsy Forcep have any such language? Certainly, reusable saw blades have no such labeling. If there were a limit on "the number of times" a reusable device can be used, who is doing the counting? Is it the number of procedures for a reusable orthopedic instrument set? Is it the number of cuts for scissors? RPMs in a drill? Sterilization cycles?

Single-use devices also have the same "safety margin" designed into the item. The OEM will say that it would be impossible to answer the same set of questions for a single-use device, but in fact, the market place knows the answer. No device has a set number of uses. Alliance see daily, single-use devices that have only been used one time, that will not pass the functionally test. Yet in the same order from the same hospital will be the same model of the same device that has previously been reprocessed. The issue to focus on is "functionality", not number of uses.

Page 8 – Question 1: Does postmarket information suggest that using the reprocessed SUD may present an increased risk of injury when compared to the use of an SUD that has not been reprocessed?

In FDA's comments, the Agency says, *"FDA believes that **existence** of significant adverse postmarket data is a compelling reason for concern and, therefore, would consider the device to be high risk."*

Comments:

The mere existence of data has never been satisfactory to the Agency in determining the safety or effectiveness of a medical device. Rather, the agency has always required valid scientific data from adequate and well-controlled studies.

The Agency has said on numerous occasions that they do not have data that shows a major health issue. As recently as February 10, 2000, Dr. David Feigal testified before the House Subcommittee on Oversight and Investigations, at which time he said:

> "Despite a lack of clear data that suggests that many injuries are occurring due to reprocessing practices, ... "

But then immediately, the Agency says, *"FDA **does not** consider the **absence** of relevant information to be either evidence of increased risk or proof of safety."*

Alliance feels that there is a great deal of inconsistency in this position. This again begs the question, "What is the need for a risk scheme that only sets timeframes for the submission of data?" As stated above, Alliance suggests that the current Class I, II, and III device categories simply be assigned timeframes. While Alliance strongly feels that the current timeframes outlined in the Enforcement Documents are too short, we believe that by narrowing the number of devices with which the Agency clearly have concerns over safety issues, a new, manageable timeline can be established for both the reprocessors and the Agency.

Page 8 – Question 2a: Are there recognized consensus performance standards, performance tests *recommended by the OEM*, or a CDRH guidance document that may be used to determined if the performance of the SUD has been altered due to reprocessing and use?

FDA says, *"OEM-recommended performance tests (e.g., manufacturer-developed tests, standards that **are not recognized**) may also be applicable."*

Comments:

Alliance requests that the language be changed to read "OEM and Third-Party Reprocessor-recommended. . . ." As responsible members of the medical device community, companies like Alliance, as well as organizations like AMDR, are willing to be partners in the development of standards.

The Agency has a history of such cooperative work, as evidenced by the recent successful resolution of the mutual concern of all stakeholders in the Remanufacturers, Rebuilders, and Servicers segment of device regulation.

Yet, as recently as the March 22, 2000 meeting of the Association for the Advancement of Medical Instrumentation (AAMI), there was an example of a "special interest group" successfully preventing meaningful standards work from being accomplished. A proposal for a new project ("Cleaning of Used Medical Instruments), submitted by Victoria Hitchins, CDRH, and Steve Goldstine, Olympus America Inc. was debated within the AAMI Decontamination Working Group of the AAMI Sterilization Standards Committee. At issue was whether "single-use" devices should be part of this project, or should it be limited to reusable devices only. Speaking passionately against the inclusion of SUDs was Josephine Torrente from The Association of Disposable Device Manufacturers (ADDM). At the conclusion of the meeting, the Decontamination Working Group recommendation to the Sterilization Standards Committee was that SUDs be included. It is important to note that this recommendation had overwhelming support of FDA, Reprocessors (represented at this meeting by Alliance Medical Corporation and AMDR) Users, and Consultants to Users.

But when the recommendation was presented to the AAMI Sterilization Standards Committee for adoption the next morning, the OEMs were successful in having SUDs removed from the "Scope of Project" language.

Alliance believes that this most recent example by ADDM (who only represents three companies that manufacturer and market SUDs), along with their history of refusing to come to the table for meaningful discussions on the subject of reprocessing single-use devices, speaks volumes as to why the language "Third-Party Reprocessor" must be added. Alliance further respectfully requests that the Third-Party Reprocessor language be added not only here but, anywhere in the Guidance Document that the OEM is cited.

Pages 26 thru 30 – Appendix 2

Alliance commented extensively earlier in this document, and has enclosed as Exhibit "A" it's listing of devices that are currently being reprocessed or may/should be considered as possible candidates in the future. The CDRH Product Code data files were used to create this listing, and the Exhibit is available to the Agency in an Excel format, should they wish to use it for further review, sorting and comparison.

Enforcement Priorities for Single-Use Devices Reprocessed be Third Parties and Hospitals

Page 2 & 3 – Introductions FDA says, *"Under the proposed strategy, devices would still be classified as class I, II, III and still have premarket notification (510(k)) or premarket approval (PMA) requirements based on that classification."*

However at the end of the page, the Agency says, *"If any device designated by the companion Risk Scheme guidance as moderate or high risk is currently exempt from premarket requirements, FDA will propose to amend its classification regulations for those devices to require premarket submissions. This will be done on a product-by-product basis."*

Comments:

Alliance believes that the Agency has mixed two separate issues in these two comments. First, when the Agency says, "FDA will propose to amend its classification regulation. . . .", does that mean changing the device from Class I to Class II? Under the Alliance proposed plan of eliminating the "risk scheme" on all devices, the Agency could publish its Worksheets 1, 2 & 3 (giving time for public comment), and then though a one or two day workshop address those devices, regardless of device classification, that a "reprocessor's submission [510(k) or PMA] would be required, and within what timeframe.

The problem with this language is that, by using the Spaulding classification approach, even the simplest Class I, exempt device might require premarket submissions. Another issue is, under what timetable for submissions would these devices that are yet to be identified fall? Until this question was answered, everyone would have to wait for FDA to do their "product-by-product" evaluation.

Page 4 & 5 – D. Why is FDA phasing in the enforcement of regulatory requirements for SUD reprocessors?

Comments:

Alliance believes that, given the fact that patient safety is of the up most concern to the Agency, the reprocessors (be they hospitals or third-party) and the OEMs, that the 6-12-18 month enforcement guideline is both unrealistic and unnecessary.

It is a recognized fact that the ability of the hospital to come into compliance with all the FDA requirements is, at best, a stretch for both the Agency (inspection, etc.) and the Hospital. By the Agency stating in the last sentence on page 5:

> *"However, FDA would not enforce these requirements for **hospitals** until six (6) months from the issuance of the final guidance document",*

and the Agency's acknowledged lack of data to support a major health crisis, it is the opinion of Alliance that the timeframe for enforcement of the Final Guidance Document should be equal, regardless of who is the "reprocessor".

Alliance suggests that an additional six (6) months be added to all categories, and that both the third-party reprocessors and hospitals, **as well as all entities (i.e. surgery centers, rehabilitation hospitals, physician offices, public health departments, home health agencies, contract management companies of central sterile departments, etc.)** be required to comply with the Final Guidance Document using the same guidelines.

Page 6 – Paragraph E, 1. Registration and Listing (Section 510 of the Act; 21 CFR Part 807): FDA says at the bottom of the page, *"The initial list of **all** SUDs that an establishment reprocesses must be reported on Form FD-2892 ("Medical Device Listing"). A separate Form FD 2892 must be submitted for **each device or device class** added to the existing list."*

Comments:

Alliance believes that the language in this paragraph is very vague, as follows:

- What does the word **"all"** mean? All individual devices? All categories of devices?
- How are the words **"each device"** different from **"device class"**. Note the word "or" in the sentence.

This language is not in keeping with the understanding and sample form that was originally agreed to by CDRH and AMDR. In fact, one AMDR company tried unsuccessfully to register the devices that they routinely reprocess, and had their entire submission returned as unacceptable.

SUGGESTION: FDA needs to submit language and a sample Listing Form so that any reprocessor will know what information is required, and the Agency's staff will know if the form is complete. Not all the Boxes on Form FD-2892 ("Medical Device Listing") will have appropriate information available or relevant to a "reprocessor".

Alliance believes that the listing of devices should follow the Product Code / Regulation Number format, and not be for a single form for each OEM within any Product Code.

Page 9 – Paragraph 6 - Labeling (Section 502 of the Act; 21 CFR Part 801)

FDA says, *"FDA has general labeling requirements regarding the name and place of manufacture and the **inclusion of adequate directions for use.**"*

Comments:

Alliance (and prior to Alliance, the three companies individually) has had our labeling reviewed by FDA in the course of normal facility inspections. Beginning at least as early as 1996, all labeling has included language that clearly sets forth the fact that the device has been reprocessed, and by what facility. In addition, the OEM's name, city and state, part number, and product description have also been included.

Alliance respectfully disagrees with the Agency for need for "inclusion of adequate directions for use". The original purchaser of the device has successfully used the product the first time, and as such, should have the original instructions for use on file, or know from experience that

the instructions are not needed or used, even on the new, first-use of the device. To place any requirements on the reprocessor to include "adequate directions for use" would create possible Trademark and Copywrite infringement issues. It should be noted that no such requirement exists for the second and future use of reusable instrumentation, because it is assumed that the "operator" of the device is familiar with the clinical intended use of the item.

SUGGESTION: Alliance believes that a more practical approach would be for the Reprocessor to include on their label, language reminding the device user to refer to the Instructions for Use originally supplied by the OEM with the device.

Page 10 – Paragraph 7(b) What do I have to demonstrate to get FDA clearance of a 510(k)?

FDA says, *"For a reprocessed SUD, the legally marketed device for comparison is generally the SUD of the original device manufacturer (OEM)."*

Comments:

This language would suggest that a 510(k) is required **for each individual device.** Alliance believes that a submission may be for a "class of devices" (i.e. stainless steel saw blades), or for a device with multiple OEMs.

SUGGESTED LANGUAGE: "For a reprocessed SUD, the legally marketed device for comparison *is the same device, and the intended clinical use will not have been changed due to reprocessing."*

Pages 12 & 13 – Paragraph 7(f) What happens after a third party or hospital reprocessor submits a 510(k) submission or a PMA application that is administratively incomplete?

Comments:

First, FDA says, *"FDA initially will review your 510(k) submission or PMA application "to make a **threshold determination** as to whether it contains **sufficient information** to begin a **substantive review.** If the submission or application **does not on its face**, contain all the information required under 21 CFR 807.87 (for 510(k)s) or 21 CFR 814.2 (for PMAs), FDA **will not review that application or submission any further and the file will be placed on hold....."**.*

Further in the same paragraph, FDA says, *"You may submit the additional information to complete the file, **but FDA does not intend to exercise the enforcement discretion described in this document for reprocessed SUDs that are not the subject of complete applications or submissions.***

Alliance believes that the current rules will not work well here for both the Agency and the reprocessor. Given the fact that the FDA reviewers will be experiencing something totally new and different in a reprocessor's submission, it is very likely that most submissions will be considered "incomplete" upon arrival at FDA. Alliance suggests that FDA include in your scheme, a timeframe in which the reprocessor can continue to submit data that the reviewer believes is required, and that during that timeframe, the use of FDA "enforcement discretion"

continues so long as the reprocessor makes a "good faith effort" to provide the reviewer with the missing information in a timely fashion. Without some type of rule that allows for continued interchange of information between the reprocessor and the reviewer and at the same time, provides the protection of FDA's enforcement discretion, reprocessing as we know it today will be dead upon arrival at FDA of the first 510(k) submission.

Also, if a submission arrives at FDA at the beginning of the timeframe assigned to the risk category (example: a submission is made in Month 1 or the 6 months assigned to high risk devices), and it is determined to not meet the "threshold" for completeness, does that mean that FDA will withdraw "enforcement discretion" at that time? Does another reprocessor who submits on day 15 of month 6 have a longer "free ride" under these guidelines? This is perhaps another reason to put all reprocessors on the same timeframe as hospitals, since the likelihood of a "complete application or submission" from this segment of the industry is very unlikely.

Finally, Alliance suggests that if 510(k)/PMA submissions are filed within the timeframe outlined in the Final Guidance Document, FDA should not "take immediate enforcement action for failure to comply with premarket requirements upon determining a 510(k) submission or PMA application is administratively incomplete", *as long as the reprocessor and the reviewer make good faith efforts to provide and request additional information.*

Page 13 – Paragraph 7(g) Can I combine several different models and brands of the same type of device into one 510(k) submission or PMA application?"

Comments:

FDA says, *"Premarket (510(k)) submissions and PMA applications are **device specific;** FDA requires a 510(k) or a PMA **for each device."***

But then in the same paragraph, FDA says, *"FDA advises reprocessors to examine **device groupings that original device manufacturers have developed** as examples of appropriate **device groupings."***

Alliance is unclear as to the direction that FDA is trying to head. First, a reprocessor should be allowed to submit an application on a device from multiple manufacturers. It seems logical that as long as the materials are the same, and the reprocessor's processes are the same for the device type (regardless of the OEM), it would be appropriate to "group" the products in the same submission. The submission would include only those OEMs that appear in the CDRH Listing data for the appropriate Product Code.

Second, it is unclear to Alliance at this time where it will find the "device groupings that the original device manufacturers have developed"?

Page 13 – Paragraph 7(h) What if I need to conduct clinical studies as part of my 510(k) submission or PMA application?"

Comments:

FDA says, *"Clinical studies of **significant** risk devices need prior FDA approval of an **investigational devices exemption (IDE)** application before the study may begin."*

Alliance believes that no IDEs should be required for any device under consideration for reprocessing. If FDA has data that supports a different conclusion, the Agency should predetermine which devices are involved, and allow time for a debate on these specific devices.

Page 15 & 16 – Section F, Paragraph 1, Parts a thru c INFORCEMENT DISCRETION PERIOD FOR PREMARKET REQUIREMENTS (Sections 513, and 515 of the Act; 21 CFR Parts 807 and 814)

Comments:

Alliance has made numerous comments throughout this document referring to the timeframe set out by FDA in this Draft. They will not be repeated here. There are some common questions that perhaps need to be considered in the Final Guidance Document.

- What is "**complete**"? Alliance suggests that this be changed to say that only a "filing" is required. A complete PMA (as we know it today for a new device) could never be put together and come in "administratively complete in 6 months.
- In 1a(3), is it realistic to believe that FDA can turn an application around and issue "an FDA order finding" or "an order approving a premarket approval application" within "six (6) months of the filing date"?
- There is no language in the draft document to address a "What do I do if there is no reply from FDA on a timely basis?" situation.

Page 17 – Top of the Page

FDA says, *"FDA intends to reexamine low risk devices, however, to see if it is appropriate for FDA to promulgate **regulations** to exempt low risk devices that are reprocessed from any premarket requirements. These decisions will be made on a **case-by-case basis.**"*

Comments:

Alliance is unclear as to the meaning to this statement for the following reasons:

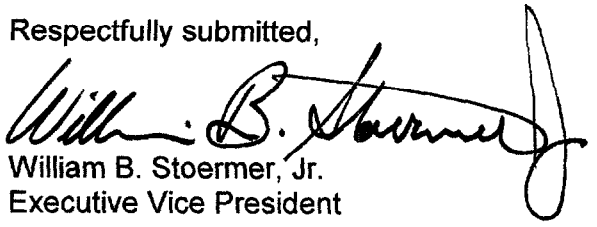
- Why "regulations" rather that another Guidance Document?
- This language sounds like Class I, exempt devices may not truly be "exempt" from "premarket requirements".

Pages 19 thru 22 – Appendix B: List of frequently reprocessed SUDs . . . . . .

Alliance Medical Corporation has included as Exhibit "A" a listing of devices (using the CDRH Product Code data) that it believes should included in any "final listing" of devices. It is not intended to be all inclusive of the industry, nor should it be. Other third-party reprocessors in the industry believe that they have the technology to reprocess devices for which Alliance chooses not to offer a reprocessing service.

Alliance Medical Corporation appreciates the opportunity to provide comments on FDA's draft guidance documents. Should you have any questions regarding the information presented in this document, please do not hesitate to contact me.

Respectfully submitted,



William B. Stoermer, Jr.
Executive Vice President

EXHIBIT "A"

ITEMS THAT ALLIANCE CURRENTLY REPORCESSES							
Medical Speciality	Device Name	Class	510k Exempt	Regulation Number	ProCode	Risk - FDA	Type of Premarket Summission
CV	CUFF, BLOOD-PRESSURE	2	N	870.112	DXQ	Low	510(k)
CV	CATHETER, INTRAVASCULAR, DIAGNOSTIC	2	N	870.12	DQO	High	510(k)
CV	CATHETER, STEERABLE	2	N	870.128	DRA		
CV	SYSTEM, CATHETER CONTROL, STEERABLE	2	N	870.129	DXX		
CV	WIRE, GUIDE, CATHETER	2	N	870.133	DQX	High	510(k)
CV	TROCAR	2	N	870.139	DRC	High Moderate	510(k)
CV	CLAMP, VASCULAR	2	N	870.445	DXC		
CV	DEVICE,STABILIZER,HEART	1	N	870.45	MWS		
CV	SLEEVE, LIMB, COMPRESSIBLE	2	N	870.58	JOW	Low	510(k)
DE	BUR, DENTAL	1	Y	872.324	EJL	Moderate	N/A
DE	SAW, BONE, AC-POWERED	2	N	872.412	DZH		
DE	DRILL, BONE, POWERED	2	N	872.412	DZI		
DE	DRIVER, WIRE, AND BONE DRILL, MANUAL	2	N	872.412	DZJ		
DE	DRILL, DENTAL, INTRAORAL	1	Y	872.413	DZA		
EN	BUR	1	Y	874.414	EQJ		
GU	SET, BIOPSY NEEDLE AND NEEDLE, GASTRO-UROLOGY	2	N	876.1075	FCG	High	510(k)
GU	PUNCH, BIOPSY	2	N	876.1075	FCI		
GU	FORCEPS, BIOPSY, NON-ELECTRIC	**1	Y	876.1075	FCL	High	510(k)
GU	INSTRUMENT, BIOPSY	2	N	876.1075	KNW		
SU	LAPAROSCOPE, GENERAL & PLASTIC SURGERY	2	N	876.15	GCJ	Low Moderate	510(k)
GU	ENDOSCOPE, AC-POWERED AND ACCESSORIES	2	N	876.15	GCP	Low Moderate	510(k)
GU	ENDOSCOPE AND/OR ACCESSORIES	2	N	876.15	KOG	Low/High	510(k)
OP	ENDOILLUMINATOR	2	N	876.15	MPA		
GU	ELECTRODE, ELECTROSURGICAL, ACTIVE, UROLOGICAL	2	N	876.43	FAS	Moderate	510(k)
GU	SNARE, FLEXIBLE	2	N	876.43	FDI		
GU	ELECTRODE, FLEXIBLE SUCTION COAGULATOR	2	N	876.43	FEH	Moderate	510(k)
GU	FORCEPS, BIOPSY, ELECTRIC	2	N	876.43	KGE	High	510(k)
GU	UNIT, ELECTROSURGICAL, ENDOSCOPIC (WITH OR WITHOUT ACCESSORIES)	2	N	876.43	KNS	Moderate High	510(k)
GU	DISLODGER, STONE, BASKET, URETERAL, METAL	2	Y	876.468	FFL		
GU	DISLODGER, STONE, FLEXIBLE	2	Y	876.468	FGO		
GU	SNARE, NON-ELECTRICAL	1	Y	876.473	FGX		
GU	HOLDER, NEEDLE	1	Y	876.473	FHQ		
SU	UNIT, ELECTROSURGICAL ANDCOAGULATION, WITH ACCESSORIES	2	N	878.44	BWA		
SU	ELECTROSURGICAL DEVICE	2	N	878.44	DWG		
SU	DEVICE, ELECTROSURGICAL, CUTTING & COAGULATION & ACCESSORIES	2	N	878.44	GEI		

EXHIBIT "A"

Medical Speciality	Device Name	Class	510k Exempt	Regulation Number	ProCode	Risk - FDA	Type of Premarket Summission
SU	APPARATUS, ELECTROSURGICAL	2	N	878.44	HAM	Moderate	510(k)
SU	ELECTRODE, ELECTROSURGICAL	2	N	878.44	JOS		
SU	KNIFE, SURGICAL	1	Y	878.48	EMF		
SU	CHISEL, SURGICAL, MANUAL	1	Y	878.48	FZO		
SU	CURETTE, SURGICAL	1	Y	878.48	FZS		
SU	CUTTER, SURGICAL	1	Y	878.48	FZT		
SU	RASP, SURGICAL, GENERAL & PLASTIC SURGERY	1	Y	878.48	GAC		
SU	RETRACTOR, SURGICAL, GENERAL & PLASTIC SURGERY	1	Y	878.48	GAD		
SU	SNARE, SURGICAL	1	Y	878.48	GAE		
SU	SPATULA, SURGICAL, GENERAL & PLASTIC SURGERY	1	Y	878.48	GAF		
SU	HOOK, SURGICAL, GENERAL & PLASTIC SURGERY	1	Y	878.48	GDG		
SU	GOUGE, SURGICAL, GENERAL & PLASTIC SURGERY	1	Y	878.48	GDH		
SU	DISSECTOR, SURGICAL, GENERAL & PLASTIC SURGERY	1	Y	878.48	GDI		
SU	CLAMP, SURGICAL, GENERAL & PLASTIC SURGERY	1	Y	878.48	GDJ		
SU	SAW, MANUAL AND ACCESSORIES	1	Y	878.48	GDR		
SU	HANDLE, SCALPEL	1	Y	878.48	GDZ	Moderate	N/A
SU	BRUSH, BIOPSY, GENERAL & PLASTIC SURGERY	1	Y	878.48	GEE		
SU	FORCEPS, GENERAL & PLASTIC SURGERY	1	Y	878.48	GEN		
SU	RETRACTOR, MANUAL	1	Y	878.48	GZW		
SU	SAW, MANUAL, AND ACCESSORIES	1	Y	878.48	HAC		
SU	SAW	1	Y	878.48	HSO		
SU	FORCEPS	1	Y	878.48	HTD		
SU	CURETTE	1	Y	878.48	HTF		
SU	RASP	1	Y	878.48	HTR		
SU	INSTRUMENT, CUTTING, ORTHOPEDIC	1	Y	878.48	HTZ		
SU	OSTEOTOME	1	Y	878.48	HWM		
SU	CLAMP	1	Y	878.48	HXD		
SU	RETRACTOR	1	Y	878.48	HXM		
SU	SPATULA, ORTHOPEDIC	1	Y	878.48	HXR		
SU	CHISEL, MASTOID	1	Y	878.48	JYD		
SU	INSTRUMENT, SURGICAL, DISPOSABLE	1	Y	878.48	KDC		
SU	HOOK, BONE	1	Y	878.48	KIK		
SU	SCISSORS, GENERAL USE, SURGICAL	1	Y	878.48	LRW	Moderate	N/A
SU	INSTRUMENT, MANUAL, GENERAL SURGICAL	1	Y	878.48	MDM		
SU	INSTRUMENT, MANUAL, SURGICAL, GENERAL USE	1	Y	878.48	MDW		
SU	BLADE, SAW, SURGICAL, CARDIOVASCULAR	1	Y	878.482	DWH	Low	N/A
SU	SAW, ELECTRICALLY POWERED	1	Y	878.482	DWI		
SU	BLADE, SAW, GENERAL & PLASTIC SURGERY, SURGICAL	1	Y	878.482	GFA	Low	N/A
SU	DERMATOME	1	Y	878.482	GFD		
SU	BUR, SURGICAL, GENERAL & PLASTIC SURGERY	1	Y	878.482	GFF	Low	N/A
SU	BIT, SURGICAL	1	Y	878.482	GFG		
SU	SAW, POWERED, AND ACCESSORIES	1	Y	878.482	HAB		
SU	CHISEL (OSTEOTOME)	1	Y	878.482	KDG		
SU	SAW, PNEUMATICALLY POWERED	1	Y	878.482	KFK		

Medical Speciality	Device Name	Class	510k Exempt	Regulation Number	ProCode	Risk - FDA	Type of Premarket Summission
SU	TOURNIQUET, NONPNEUMATIC	1	Y	878.59	GAX		
SU	TOURNIQUET, PNEUMATIC	1	Y	878.591	KCY		
NE	DRILLS, BURRS, TREPHINES & ACCESSORIES (MANUAL)	2	N	882.43	HBG		
NE	DRILLS, BURRS, TREPHINES & ACCESSORIES (COMPOUND, POWERED)	2	N	882.4305	HBF		
NE	DRILLS, BURRS, TREPHINES & ACCESSORIES (SIMPLE, POWERED)	2	N	882.431	HBE		
OB	LAPAROSCOPE, GYNECOLOGIC (AND ACCESSORIES)	**2	N	884.172	HET	Low/High	N/A, 510(k)
OB	ELECTROCAUTERY, ENDOSCOPIC AND ACCESSORIES	3	N	884.41	HIM		
OB	ELECTROCAUTERY, GYNECOLOGIC (AND ACCESSORIES)	2	N	884.412	HGI		
OB	COAGULATOR-CUTTER, ENDOSCOPIC, BIPOLAR (AND ACCESSORIES)	3	N	884.415	HIN		
OB	COAGULATOR, LAPAROSCOPIC, UNIPOLAR (AND ACCESSORIES)	2	N	884.416	HFG		
OB	COAGULATOR, HYSTEROSCOPIC (AND ACCESSORIES)	2	N	884.416	HFH		
OB	COAGULATOR, CULDOSCOPIC (AND ACCESSORIES)	2	N	884.416	HFI		
OB	COAGULATOR-CUTTER, ENDOSCOPIC, UNIPOLAR (AND ACCESSORIES)	2	N	884.416	KNF		
OB	FORCEPS, BIOPSY, GYNECOLOGICAL	1	Y	884.453	HFB	High	510(k)
OP	KNIFE, OPHTHALMIC	1	Y	886.435	HNN		
OP	KERATOME,WATER JET	1	N	886.437	MYD	High	510(k)
OP	FLUIDIC, PHACOEMULSIFICATION/PHACOFRAGMENTATION	2	N	886.467	MUS	High	510(k)
OR	SCISSORS	1	Y	888.454	HRR		
OR	REAMER	1	Y	888.454	HTO		
OR	KNIFE, ORTHOPEDIC	1	Y	888.454	HTS		
OR	BURR	1	Y	888.454	HTT		
OR	BIT, DRILL	1	Y	888.454	HTW	Low	N/A
OR	RONGEUR	1	Y	888.454	HTX		
OR	TREPHINE	1	Y	888.454	HWK		
OR	COUNTERSINK	1	Y	888.454	HWW		
OR	TAP, BONE	1	Y	888.454	HWX		
OR	HOLDER, NEEDLE; ORTHOPEDIC	1	Y	888.454	HXK		
PM	CABLE, ELECTRODE	1	Y	890.1175	IKD		
	ITEMS THAT ALLIANCE IS CONSIDERING FOR REPROCESSING						
GU	DISLODGER, STONE, BILIARY		Y		LQR		
AN	CIRCUIT, BREATHING (W CONNECTOR, ADAPTOR, Y PIECE)	1	Y	868.524	CAI	Moderate	N/A
AN	CATHETER, NASAL, OXYGEN	1	Y	868.535	BZB	Low	N/A
AN	MASK, GAS, ANESTHETIC	1	Y	868.555	BSJ	Low	N/A
AN	MOUTHPIECE, BREATHING	1	Y	868.562	BYP	Low	N/A
AN	FORCEPS, TUBE INTRODUCTION	1	Y	868.578	BWB		
CV	CATHETER, SUCTION, TRACHEOBRONCHIAL	1	Y	868.681	BSY	High	510(k)
CV	CATHETER, CONTINUOUS FLUSH	2	N	870.121	KRA		
CV	CATHETER, ELECTRODE RECORDING, OR PROBE, ELECTRODE RECORDING	2	N	870.122	DRF	High	510(k)
CV	CATHETER,INTRACARDIAC MAPPING,HIGH-DENSITY ARRAY	2	N	870.122	MTD		
CV	CATHETER, OXIMETER, FIBEROPTIC	2	N	870.123	DQE		
CV	CATHETER, FLOW DIRECTED	2	N	870.124	DYG		

Medical Speciality	Device Name	Class	510k Exempt	Regulation Number	ProCode	Risk - FDA	Type of Premarket Summission
CV	CANNULA, CATHETER	2	N	870.13	DQR		
NE	GUIDE, WIRE, CATHETER, NEUROVASCULATURE	2	N	870.133	MOF		
CV	INTRODUCER, CATHETER	2	N	870.134	DYB		
CV	OCCLUDER, CATHETER TIP	2	N	870.137	DQT		
CV	STYLET, CATHETER	2	N	870.138	DRB		
CV	INJECTOR AND SYRINGE, ANGIOGRAPHIC	2	N	870.165	DXT	High	510(k)
CV	CABLE, TRANSDUCER AND ELECTRODE, PATIENT, (INCLUDING CONNECTOR)	2	N	870.29	DSA		
CV	CLIP, VASCULAR	2	N	870.325	DSS		
CV	CLIP, VENA-CAVA	2	N	870.326	DST		
CV	TUBING, PUMP, CARDIOPULMONARY BYPASS	2	N	870.439	DWE	High	N/A
DE	CURETTE, OPERATIVE	1	Y	872.4565	EKE		
DE	CURETTE, ENDODONTIC	1	Y	872.4565	EKT		
DE	CURETTE, SURGICAL, DENTAL	1	Y	872.4565	EMK		
DE	CHISEL, BONE, SURGICAL	1	Y	872.4565	EML		
DE	CHISEL, OSTEOTOME, SURGICAL	1	Y	872.4565	EMM		
DE	CURETTE, PERIODONTIC	1	Y	872.4565	EMS		
DE	LIGHT, FIBER OPTIC, DENTAL	1	Y	872.462	EAY		
DE	LIGHT, OPERATING, DENTAL	1	Y	872.463	EAZ		
DE	LIGHT, SURGICAL HEADLIGHT	1	Y	872.463	EBA		
DE	EXTERNAL MANDIBULAR FIXATOR AND/OR DISTRACTOR	2	N	872.476	MQN		
DE	BAND, MATERIAL, ORTHODONTIC	1	Y	872.541	DYO		
DE	WIRE, ORTHODONTIC	1	Y	872.541	DZC		
DE	TUBE, ORTHODONTIC	1	Y	872.541	DZD		
DE	BAND, ELASTIC, ORTHODONTIC	1	Y	872.541	ECI		
DE	BAND, PREFORMED, ORTHODONTIC	1	Y	872.541	ECM		
DE	CLAMP, WIRE, ORTHODONTIC	1	Y	872.541	ECN		
DE	SPRING, ORTHODONTIC	1	Y	872.541	ECO		
DE	BRACKET, METAL, ORTHODONTIC	1	Y	872.541	EJF	High	N/A
DE	BRACKET, PLASTIC, ORTHODONTIC	2	N	872.547	DYW	High	510(k)
EN	SET, FILLIFORM, EUSTACHIAN	1	Y	874.4175	KBY		
EN	KNIFE, MYRINGOTOMY	1	Y	874.442	JYP		
EN	PERFORATOR, EAR-LOBE	1	Y	874.442	JYS		
EN	RASP, EAR	1	Y	874.442	JYY		
EN	SCISSORS, EAR	1	Y	874.442	JZB	Moderate	N/A
EN	TROCAR, LARYNGEAL	1	Y	874.442	KAB	Moderate	N/A
EN	KNIFE, NASAL	1	Y	874.442	KAS	Moderate	N/A
EN	SCISSORS, NASAL	1	Y	874.442	KBD	Moderate	N/A
EN	TROCAR, SINUS	1	Y	874.442	KBG	Moderate	N/A
EN	KNIFE, TONSIL	1	Y	874.442	KBQ	Moderate	N/A
EN	TROCAR, TRACHEAL	1	Y	874.442	KCI	Moderate	N/A
EN	KNIFE, ENT	1	Y	874.442	KTG		
EN	TRACHEOTOME	1	Y	874.442	LJW		
EN	LASER, MICROSURGICAL ARGON, FOR USES OTHER THAN OTOLOGY, INCLUDING LARYNGOLOGY	2	N	874.449	LMS	Low	510(k)
EN	LASER, MICROSURGICAL ARGON, FOR USE IN OTOLOGY	2	N	874.449	LXR	Low	510(k)

Medical Speciality	Device Name	Class	510k Exempt	Regulation Number	ProCode	Risk - FDA	Type of Premarket Summission
EN	LASER, ENT MICROSURGICAL CARBON-DIOXIDE	2	N	874.45	EWG	Low	510(k)
EN	FORCEPS, BIOPSY, BRONCHOSCOPE (RIGID)	2	N	874.468	JEK		
GU	BRUSH, CYTOLOGY, FOR ENDOSCOPE	2	N	876.15	FDX		
GU	ILLUMINATOR, FIBEROPTIC, FOR ENDOSCOPE	2	N	876.15	FFS		
GU	CORD, ELECTRIC, FOR ENDOSCOPE	2	N	876.15	FFZ		
GU	ENDOSCOPE, DIRECT VISION	2	N	876.15	GCR	Low Moderate	510(k)
CV	ANGIOSCOPE	2	N	876.15	LYK		
GU	SNARE, RIGID SELF-OPENING	2	N	876.43	FDJ		
GU	TROCAR, GASTRO-UROLOGY	2	N	876.509	FBQ	Low Moderate	510(k)
GU	CATHETER, MALECOT	2	N	876.509	FEW		
GU	CATHETER AND TUBE, SUPRAPUBIC	2	N	876.509	FEZ		
GU	CATHETER, SUPRAPUBIC (AND ACCESSORIES)	2	N	876.509	KOB		
GU	CATHETER, URETERAL, GASTRO-UROLOGY	2	N	876.513	EYB		
GU	CATHETER, UPPER URINARY TRACT	2	N	876.513	EYC		
GU	ADAPTOR, URETERAL CATHETER	1	Y	876.513	EYI		
GU	HOLDER, URETERAL CATHETER	1	Y	876.513	EYJ		
GU	CONNECTOR, URETERAL CATHETER	1	Y	876.513	EYK		
GU	STYLET FOR CATHETER, GASTRO-UROLOGY	1	Y	876.513	EZB		
GU	CATHETER, COUDE	2	N	876.513	EZC		
GU	CATHETER, STRAIGHT	2	N	876.513	EZD		
GU	CATHETER, DOUBLE LUMEN FEMALE URETHROGRAPHIC	2	N	876.513	FGH		
GU	CATHETER, UROLOGICAL	2	N	876.513	KOD	Moderate	510(k)
GU	FILIFORM AND FILIFORM FOLLOWER	1	Y	876.552	FBW		
GU	CATHETER, HEMODIALYSIS, NON-IMPLANTED	2	N	876.554	MPB		
GU	CATHETER, PERITONEAL DIALYSIS, SINGLE USE	2	N	876.563	FKO		
SU	SPLINT, EXTREMITY, INFLATABLE, EXTERNAL	1	Y	878.39	FZF	Low	N/A
SU	SPLINT, EXTREMITY, NONINFLATABLE, EXTERNAL	1	Y	878.391	FYH	Low	N/A
SU	SCALPEL, ONE-PIECE	1	Y	878.48	GDX	Moderate	N/A
SU	FILE, SURGICAL, GENERAL & PLASTIC SURGERY	1	Y	878.48	GEO		
A	BLADE, SCALPEL	1	Y	878.48	GES	Moderate	N/A
SU	APPLIER, HEMOSTATIC CLIP	1	Y	878.48	HBT	Moderate	N/A
SU	CANNULA, SINUS	1	Y	878.48	KAM		
SU	CHISEL, NASAL	1	Y	878.48	KAN		
SU	KIT, SURGICAL INSTRUMENT, DISPOSABLE	1	Y	878.48	KDD		
SU	LASER INSTRUMENT, SURGICAL, POWERED	2	N	878.481	GEX	Low	510(k)
SU	MOTOR, SURGICAL INSTRUMENT, PNEUMATIC POWERED	1	Y	878.482	GET	Low	N/A
SU	MOTOR, SURGICAL INSTRUMENT, AC-POWERED	1	Y	878.482	GEY	Low	N/A
NE	ELECTRODE, NEEDLE	2	N	882.135	GXZ		
NE	PROBE, RADIOFREQUENCY LESION	2	N	882.4725	GXI		
OB	BRUSH, ENDOMETRIAL	3	N	884.11	HFE		

Medical Speciality	Device Name	Class	510k Exempt	Regulation Number	ProCode	Risk - FDA	Type of Premarket Summission
OB	CURETTE, SUCTION, ENDOMETRIAL (AND ACCESSORIES)	2	N	884.1175	HHK		
OB	SCISSORS, UMBILICAL	1	Y	884.452	HDJ	Moderate	N/A, 510(k)
OB	SCISSORS, EPISIOTOMY	1	Y	884.452	HDK	Moderate	510(k)
OB	CLAMP, UTERINE	1	Y	884.452	HGC		
OB	CURETTE, UTERINE	1	Y	884.453	HCY		
OB	CLAMP, UMBILICAL	2	N	884.453	HFW		
OB	CLAMP, CIRCUMCISION	2	N	884.453	HFX		
OB	LASER, SURGICAL, GYNECOLOGIC	2	N	884.455	HHR*	Low	N/A, 510(k)
OB	LASER, NEODYMIUM:YAG FOR GYNECOLOGIC USE	2	N	884.455	LLW	Low	510(k)
OP	DEVICE, FIXATION, AC-POWERED, OPHTHALMIC	1	Y	886.13	HPL		
OP	BURR, CORNEAL, BATTERY-POWERED	1	N	886.407	HOG		
OP	BURR, CORNEAL, AC-POWERED	1	N	886.407	HQS		
OP	ENGINE, TREPHINE, ACCESSORIES, BATTERY-POWERED	1	N	886.407	HRF		
OP	ENGINE, TREPHINE, ACCESSORIES, AC-POWERED	1	N	886.407	HRG	Low	N/A
OP	UNIT, CAUTERY, THERMAL, AC-POWERED	2	N	886.4115	HQO		
OP	UNIT, CAUTERY, THERMAL, BATTERY-POWERED	2	N	886.4115	HQP		
OP	INSTRUMENT, VITREOUS ASPIRATION AND CUTTING, BATTERY-POWERED	2	N	886.415	HKP		
OP	INSTRUMENT, VITREOUS ASPIRATION AND CUTTING, AC-POWERED	2	N	886.415	HQE		
OP	SPATULA, OPHTHALMIC	1	Y	886.435	HND		
OP	SNARE, ENUCLEATING	1	Y	886.435	HNE		
OP	SCISSORS, OPHTHALMIC	1	Y	886.435	HNF		
OP	HOOK, OPHTHALMIC	1	Y	886.435	HNQ		
OP	FORCEPS, OPHTHALMIC	1	Y	886.435	HNR		
OP	CURETTE, OPHTHALMIC	1	Y	886.435	HNZ		
OP	CLAMP, MUSCLE, OPHTHALMIC	1	Y	886.435	HOB		
OP	BURR, CORNEAL, MANUAL	1	Y	886.435	HOF		
OP	TREPHINE, MANUAL, OPHTHALMIC	1	Y	886.435	HRH		
OP	KERATOME, BATTERY-POWERED	1	N	886.437	HMY	High	510(k)
OP	KERATOME, AC-POWERED	1	N	886.437	HNO	High	510(k)
OP	PHOTOCOAGULATOR AND ACCESSORIES	2	N	886.469	HQB	Low	510(k)
OR	STRIPPER, SURGICAL	1	Y	888.454	HRT		
OR	FILE	1	Y	888.454	HTP		
OR	BROACH	1	Y	888.454	HTQ		
OR	PASSER, WIRE, ORTHOPEDIC	1	Y	888.454	HXI		
PM	CABLE	1	Y	890.342	ISN		
SU	INSTRUMENT, DISPOSAL, SURGICAL (SHARPS)		N		KDB		
SU	INSTRUMENT, ULTRASONIC SURGICAL		N		LFL		
CV	CATHETER, ANGIOPLASTY, PERIPHERAL, TRANSLUMINAL		N		LIT	High	510(k)
NE	CATHETER, STEERABLE CEREBROVASCULAR	3	N		LJA		
NE	LASER, NEUROSURGICAL	3	N		LKW		
CV	LEGGING, COMPRESSION, NON-INFLATABLE		N		LLK	High	PMA
CV	CATHETERS, TRANSLUMINAL CORONARY ANGIOPLASTY, PERCUTANEOUS & OPERATIVE	3	N		LOX	High	PMA
CV	DEVICE, ANGIOPLASTY, LASER, CORONARY	3	N		LPC		

EXHIBIT "A"

Medical Speciality	Device Name	Class	510k Exempt	Regulation Number	ProCode	Risk - FDA	Type of Premarket Summission
SU	PUNCH, SURGICAL		N		LRY		
OR	ACCESSORIES, FIXATION, SPINAL INTERLAMINAL		N		LYP		
OR	ACCESSORIES, FIXATION, SPINAL INTERVERTEBRAL BODY		N		LYQ		
OR	FIXATION ACCESSORY		N		LYT		
OB	CATHETERS, SALPINGOGRAPHY		N		MOV		
OR	CAST,STOCKING,ANTI-MICROBIALS		Y		MTT		

SNA21

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1 ☐ Hold Weekday (Not available with FedEx First Overnight) 31 ☐ Hold Saturday (Not available at all locations) (Available for FedEx Priority Overnight and FedEx 2Day only)

For WEEKEND Delivery check here (Extra Charge, Not available at all locations)

3 ☐ Saturday Delivery (Available for FedEx Priority Overnight and FedEx 2Day only) 33 ☐ NEW Sunday Delivery (Available for FedEx Priority Overnight only)

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4a Express Package Service *Packages under 150 lbs.* Delivery commitment may be later in some areas.

1 ☒ FedEx Priority Overnight (Next business morning) 5 ☐ FedEx Standard Overnight (Next business afternoon)

6 ☐ FedEx First Overnight (Earliest next business morning delivery to select locations) (Higher rates apply)

3 ☐ FedEx 2Day (Second business day) 20 ☐ FedEx Express Saver (Third business day)

FedEx Letter Rate not available. Minimum charge: One pound rate.

4b Express Freight Service *Packages over 150 lbs.* Delivery commitment may be later in some areas.

7 ☐ FedEx Overnight Freight (Next business day) 8 ☐ FedEx 2Day Freight (Second business day) 83 ☐ FedEx Express Saver Freight (Up to 3 business days)

(Call for delivery schedule. See back for detailed descriptions of freight services.)

5 Packaging 6 ☒ FedEx Letter 2 ☐ FedEx Pak 3 ☐ FedEx Box 4 ☐ FedEx Tube 1 ☐ Other Pkg.

Declared value limit $500.

6 Special Handling (One box must be checked)

Does this shipment contain dangerous goods?* ☐ No 4 ☐ Yes (As per attached Shipper's Declaration) ☐ Yes (Shipper's Declaration not required)

6 ☐ Dry Ice Dry Ice, 9, UN 1845 _____ x _____ kg. CA ☐ Cargo Aircraft Only

*Dangerous Goods cannot be shipped in FedEx packaging.

7 Payment ☐ Obtain Recipient FedEx Account No.

Bill to: 1 ☒ Sender (Account No. in Section 1 will be billed) 2 ☐ Recipient 3 ☐ Third Party 4 ☐ Credit Card 5 ☐ Cash/Check

(Enter FedEx Account No. or Credit Card No. below)

FedEx Account No. _____

Credit Card No. _____ Exp. Date _____

Total Packages _____ Total Weight _____

Total Charges $ _____

Credit Card Auth.

* When declaring a value higher than $100 per shipment, you pay an additional charge. See SERVICE CONDITIONS, DECLARED VALUE, AND LIMIT OF LIABILITY section for further information.

8 Release Signature

Your signature authorizes Federal Express to deliver this shipment without obtaining a signature and agrees to indemnify and hold harmless Federal Express from any resulting claims.

321

WCSL 0299
Rev. Date 7/98
Part #153023ps

PRINTED IN U.S.A.

0090011865